REMARKS

The Non-Final Office Action mailed August 25, 2010, has been received and reviewed. Prior to the present communication, claims 32-52 were pending in the subject application. All pending claims stand rejected. In particular, claims 39 and 50 were rejected under 35 U.S.C. § 112 and 101, while all claims were rejected under 35 U.S.C. § 103(a). Each of claims 32, 34-36, 39, 41, and 48-50 has been amended herein, while no claims have been canceled or added. As such, claims 32-52 remain pending. It is submitted that no new matter has been added by way of the present amendments. Reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

Support for Claim Amendments

Independent claims 32, 41, and 49 have been amended herein to recite a clarification of the process of using test results from specific family members of the patient to determine a likelihood that the patient expresses a mutated form of a gene—when the patient does not have genetic test results for the gene. In particular, with respect to claim 32, the process now involves:

- "when the first database indicates that the person does not have the one or more genetic test results for the gene, identifying an appropriate traversal pattern of the gene within a family of the person identified, wherein the traversal pattern of the gene is identified by a process comprising:"
    - "*accessing an inference table that associates genes with a plurality of modes of inheritance*;"
    - "*querying the inference table with the gene to select a mode of inheritance that corresponds with the gene*;" and

- "*using the selected mode of inheritance to determine the traversal pattern of the gene within the person's family*;" and

- "identifying at least one family member within the identified traversal pattern of the person's family for inspection."

Support for these claim amendments may be found in the Specification, for example, at paragraphs [0037], [0038], [0040], [0050] – [0056], and at FIGS. 2B and 3. Specifically, support for the inference table may be found in the Specification at paragraphs [0047] – [0050], and at Table 1 on page 14.

In general, amendments to the claimed subject matter are not "new matter" within meaning of 35 U.S.C. § 132 or Rule 118 of Patent Office Rules of Practice, unless they disclose an invention, process, or apparatus not theretofore described. Further, if later-submitted material simply clarifies or completes prior disclosure, it cannot be treated as "new matter."[1] By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, "a patent application *necessarily discloses* that function, theory or advantage, even though it says nothing explicit concerning it" (emphasis added).[2] The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.[3] Accordingly, because these amendments are explicitly discussed, and/or inherent to, the procedure of inferring genetic findings for a patient, as memorialized in the Detailed Description, the newly recited subject matter is encompassed by the scope of the Specification and does not constitute new matter.

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[1] *Triax Co. v Hartman Metal Fabricators, Inc.*, 479 F2d 951 (1973, CA2 NY); cert. denied, 94 S. Ct. 843 (1973).

[2] *See* MPEP § 2163.07; *In re Reynolds*, 443 F.2d 384 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376 (CCPA 1973).

[3] *See id.*

Rejections base on 35 U.S.C. § 112

Dependent claims 36 and 50 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, the term "instructions" has been removed from the rejected claims, rendering the pending 112 rejection moot.

Further, claims 36 and 50 are amended to recite the provision of computer-storage media (CSM) for the execution of a method step. In this way, it is clear that the CSM carries out at least one method step and involves an article of manufacture to accomplish this task.

Rejections based on 35 U.S.C. § 101

Dependent claims 36 and 50 were rejected under 35 U.S.C. § 101 for being directed toward non-statutory subject matter. In particular, the Office indicates that the Specification defines computer-storage media (CSM) as includes an embodiment of "information as a signal."

In order to expedite allowance of the rejected claims, without conceding to the validity of the Office's contentions, dependent claims 36 and 50 are amended to recite the term "non-transitory," per the Examiner's suggestion. Additionally, the amendment is made per the Office's suggestion.[4] Including the term "non-transitory" clarifies that a mere fleeting signal is excluded from the scope of what is meant by "computer-storage media" to the extent that the same would otherwise render the claim unpatentable in view of the current state of the law.

Claims 36 and 50, as amended, can be classified as, at least, articles of manufacture and, thus, fall within the expressed scope of § 101. In Nuijten,[5] the Court of Appeals for the Federal Circuit pronounced that signals inherently require some physical form

[4] *Interim Examination Instructions for Evaluating Subject Matter Eligiblity Under 35 U.S.C. § 101* dated August 24, 2009.

and implicitly rely on a physical carrier; however, transitory embodiments of signals are not directed toward statutory subject matter. When amended to recite "non-transitory," claims 36 and 50 preclude non-statutory transitory embodiments. That is, each of the dependent claims 36 and 50 embrace patent-eligible subject matter and do not encompass any embodiments within a judicially recognized exception.

Rejections based on 35 U.S.C. § 103

A.) Obviousness rejection based upon U.S. Patent No. 6,112,182 to Akers et al. in view of WO 2001/01218 to Denton et al. and in view of IDS of 04/12/2004 to Harris in view of "Automatic Computation of Generic Risk" to Pathak et al.

Claims 32-40 were rejected under 35 U.S.C. § 103(a) as being obvious over Akers et al.[6] (hereinafter Akers) in view of Denton et al.[7] (hereinafter Denton), Harris et al.[8] (hereinafter Harris), and Pathak et al.[9] (hereinafter Pathak). As the proposed combination of the Akers, Denton, Harris, and Pathak references does not describe, either expressly or inherently, each and every element of amended independent claim 32, or the claims that depend therefrom, the Applicants respectfully consider the pending rejection of these claims overcome, as hereinafter set forth.

Independent claims 32, 41, and 49 have been amended herein to recite a clarification of the process of using a genetic finding of a patient's family members to determine a likelihood the patient expresses a mutated form of a gene—when the patient does not have genetic test results for the gene. In particular, with respect to claim 32, the process now involves:

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[5] *In re Nuijten*, 500 F.3d 1346, 1353 (Fed. Cir. 2007).
[6] U.S. Patent No. 6,112,182.
[7] WO 2001/01218.
[8] IDS 04/12/2004, NPL reference 1.
[9] "Automatic Computation of Generic Risk," Department of Computer Science, Carnegie Mellon University.

- "when the first database indicates that the person does not have the one or more genetic test results for the gene, identifying an appropriate traversal pattern of the gene within a family of the person identified, wherein the traversal pattern of the gene is identified by a process comprising:"
    - "*accessing an inference table that associates genes with a plurality of modes of inheritance*;"
    - "*querying the inference table with the gene to select a mode of inheritance that corresponds with the gene*;" and
    - "*using the selected mode of inheritance to determine the traversal pattern of the gene within the person's family*;" and
- "identifying at least one family member within the identified traversal pattern of the person's family for inspection."

In this way, the mode of inheritance (e.g., mitochondrial DNA mode, autosomal mode, X-linked mode, and Y-linked mode)[10] is selected based on the gene and utilized to determine which members of the person's family to examine based on the traversal pattern of laid out by the mode of inheritance of the gene. That is, the inheritance information regarding a particular gene is now applied to select appropriate family members to investigate for genetic information within a healthcare setting. Advantageously, only a select number of family members (according to the traversal pattern) are subject to analysis, thereby creating efficiencies in the system by saving time searching for irrelevant family members and processing resources.

[10] *See* Specification at FIG. 3, reference numeral 60, and at ¶¶ [0051] – [0054].

The teachings or suggestions to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure.[11] To establish a *prima facie* case of obviousness, all the claim limitations must be taught by the prior art.[12] When determining whether a claim limitation is taught, "All words in a claim must be considered in judging the patentability of that claim against the prior art."[13]

The Office indicates that Harris describes the determination of a mode of inheritance for a gene. In particular, during the Examiner Interview, the Examiner pointed to Figure 6 on page 43 of Harris to illustrate an a table with family statistics used to predict the probability an offspring will express a genetic trait. However, Harris does not describe (a) a table that associates a clinical agent with the gene(s) that indicate an adverse reaction, or (b) an inference table that associates the gene with a mode of inheritance, which is used to identify an appropriate traversal pattern of the gene within a family of the person (pinpointing the relevant family members for review). Instead, Harris simply employs a system that outputs the probability a person in a pre-modeled family will express a trait already known to be present within member of the family.[14] That is, Harris focuses on developing a pedigree chart that compiles a family history of a genotype; however, Harris does not consider the elements (a) and (b) for applying a mode of inheritance within a healthcare setting.

The Office concedes that neither the Akers reference nor the Denton reference teach the elements (a) and (b) above. Yet, the Office relies on Pathak to teach using a set of rules to identify a route of inheritance of the mutation based on familial relationships. However, Pathak does not describe the elements (a) and (b) to apply a mode of inheritance within a healthcare setting. Instead, Pathak identifies set of alleles already known to be present within a

[11] *See* MPEP § 2143; *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).
[12] MPEP § 2143.03; *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974).

child and at least one parent and compares the identified alleles to trace the allele's manner of inheritance.[15] As such, Pathak requires knowledge of the genetic information of various relatives prior to identifying a flow of an allele. The amended independent claims seek to avoid inspecting various members of the family that do not express the gene associated with the clinical agent being administered to the patient. Advantageously, the proper family members are identified as candidates for examination without performing any initial genetic testing. Therefore, the cited references do not teach or suggest each and every element of the amended independent claim. Accordingly, Applicants respectfully request withdrawal of the § 103(a) rejection.

B.) Obviousness rejection based upon Akers in view of Denton in view of Pathak in view of Harris in view of Hum. Mol. Gen., Vol. 5, No. 1 to Wijker et al. and in view of PNAS, Vol. 81 to Lathrop et al.

Claims 41-48 were rejected under 35 U.S.C. 103(a) as being unpatentable over Akers in view of Denton, Pathak, Harris, Wijker et al.[16] (hereinafter Wijker), and Lathrop et al.[17] (hereinafter Lathrop). As discussed above, neither the Akers, Denton, Harris, nor Pathak references teach or suggest all of the limitations of the amended independent claims. It is respectfully submitted that the Wijker and Lathrop references fail to cure at least the above-discussed deficiencies of the Akers, Denton, Harris, and Pathak references. More particularly, it is respectfully submitted that Wijker and Lathrop fail to teach or suggest elements (a) and (b) to apply a mode of inheritance within a healthcare setting. Rather, the Wijker reference is cited to disclose a method for employing a multi-locus linkage analysis for identifying a location of a

[13] MPEP § 2143.03; *In re Wilson*, 57 C.C.P.A. 1029, 1032 (1970).
[14] *Harris* at pg. 37, col. 2.
[15] *Pathak* at pg. 166, cols. 1 and 2.
[16] Hum. Mol. Gen., Vol. 5, No. 1. P. 151-154 (1996).
[17] PNAS, Vol. 81, p. 3443-3446 (1984).

gene on a chromosome,[18] while Lathrop is cited for an algorithm that performs multi-locus linkage analysis to improve the efficiency of a genetic map.[19] Accordingly, it is respectfully submitted that the Denton, Pathak, Harris, Wijker, and Lathrop references, whether taken alone or in combination, fail to teach or suggest all of the limitations of the amended independent claims 32, 41, and 49, and, accordingly, of claims 42-48.[20]

C.) Obviousness rejection based upon Akers in view of Denton in view of Harris in view of Pathak and in view of Am. J. Hum. Genet., Vol.66

Claims 49-52 were rejected under 35 U.S.C. 103(a) as being unpatentable over Akers in view of Denton, Harris, Pathak, and Pratt et al.[21] (hereinafter Pratt). As discussed above, neither the Akers, Denton, Harris, nor Pathak references teach or suggest all of the limitations of the amended independent claims. It is respectfully submitted that Pratt fails to cure at least the above-discussed deficiencies of the Akers, Denton, Harris, and Pathak references. More particularly, it is respectfully submitted that Pratt fails to teach or suggest elements (a) and (b) to apply a mode of inheritance within a healthcare setting. Rather, the Pratt reference is cited to disclose a method combining pedigree analysis and QTL analysis.[22] Accordingly, it is respectfully submitted that the Denton, Pathak, Harris, and Pratt references, whether taken alone or in combination, fail to teach or suggest all of the limitations of the amended independent claims 32, 41, and 49, and, accordingly, of claims 50-52.[23]

[18] *Wijker* at Abstract.
[19] *Lathrop* at pg. 3445, col. 1.
[20] *See* 37 C.F.R. § 1.75(c) (2006).
[21] Am. J. Hum. Genet., Vol. 66, p. 1153-1157, 2000.
[22] *Pratt* at pg. 1555, col. 2.
[23] *See* 37 C.F.R. § 1.75(c) (2006).

CONCLUSION

For at least the reasons stated above, each of claims 32-52 is believed to be in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned—by telephone at 816.559.2136 or via email at btabor@shb.com (such communication via email is herein expressly granted)—to resolve the same prior to issuing a subsequent action.

The fee for a Two-Month Extension of Time is submitted herewith. It is believed that no additional fee is due in conjunction with the present communication. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing attorney docket number CRNI.107055.

Respectfully submitted,

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